IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dahm *et al.*

Serial No.: 09/601,645
Confirmation No.: 7793

Filed: August 4, 2000

For: *METHOD FOR THE QUANTITATIVE DETERMINATION OF TUMOR CELLS IN A BODY FLUID AND TEST KITS SUITABLE THEREOF*

Art Unit: 1655

Examiner: Zitomer, S.

I hereby certify that this paper and the attached papers are being deposited with the United States Postal Service as first class mail in an envelope addressed to:
Commissioner for Patents
Washington, D.C. 20231, on this date.

06/01/01
Date

Stephanie Seidman

ELECTION

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Responsive to the Requirement for Restriction, mailed May 1, 2001, applicant elects, with traverse, group I, claims 1-38 and 52-67, directed to a nucleic acid amplification method.

REMARKS

Any fees that may be due in connection with filing this paper may be charged to Deposit Account No. 50-1213. If a Petition for Extension of time is needed, this paper is to be considered such Petition.

Traverse of finding of lack of unity

The Examiner, recognizing that the rules of unity of invention under PCT Rule 13.1 apply to the instant case, urges that there is a lack of unity because the two groups do not relate to a single inventive concept. This conclusion is based upon the premise that the single general inventive feature between the two group is "mRNA encoding the catalytic subunit of human telomerase." The Examiner urges that this mRNA is known (Genbank) and also urges that the method for quantifying mRNA is known in the art (U.S. Patent No. 5,726,019). Applicant respectfully disagrees.

Claims in group I are directed to methods for quantification of tumor cells in a body fluid by concentrating or depleting tumor cells in a sample of a body fluid; (b)

specifically amplifying mRNA coding for the catalytic subunit of telomerase; and then quantitatively determining the amount of amplified nucleic acid to thereby quantifying tumor cells in a body fluid. Dependent claims specify particulars of the method, including the primers.

Claims in group II are directed to specific primers and to a kit containing the primers.

Cited art

U.S. Patent No. 5,726,019

This patent describes a method for diagnosing lung neoplasia and is based upon the discover that a nucleic acid molecule that has as particular mutation is associated with lung neoplasia and that this nucleic acid molecule is present in detectable levels in sputum specimens from patients with lung neoplasia. U.S. Patent No. 5,726,019 does not teach or suggest that the amount of mRNA encoding a catalytic subunit telomerase can be used to quantify tumor cells in a body fluid. U.S. Patent No. 5,726,019 does not teach or suggest anything regarding telomerase or mRNA coding for the catalytic subunit of telomerase.

Genbank submission

The Examiner states that the sequence of cDNA from mRNA encoding the catalytic subunit of telomerase is available from Genbank. Even assuming that such sequence is known, the disclosure thereof provides no teaching suggestion that the amount of mRNA present in a body fluid can be used to quantitate tumor cells. Furthermore, the Genbank submission does not teach or suggest the particular primers used in the instant methods or kits.

Therefore, the instant claims are clearly novel and are not taught or suggested by the combination of teachings of the cited references. Furthermore, the instant application teaches that the quantity of mRNA that encodes the catalytic subunit of telomerase correlates with telomerase activity better than the quantity of the RNA telomerase component (International PCT application No. 97/18322; see, U.S. application Serial No. 09/068,821). Furthermore, neither reference, singly or in combination teaches or suggests the instantly claimed primers, used in the method and specified in dependent claims, and kits.

specifically amplifying mRNA coding for the catalytic subunit of telomerase; and then quantitatively determining the amount of amplified nucleic acid to thereby quantifying tumor cells in a body fluid. Dependent claims specify particulars of the method, including the primers.

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Therefore, the claims of group I and II do not lack unity and are so linked as to form a single inventive concept *i.e.* a method for quantifying tumor cells in a body fluid and primers used in the method. Accordingly, withdrawal of the lack of unity objection and restriction requirement is respectfully requested.

Claim for priority

The Examiner states that a translation of the German priority document has not been provided, and that as a result the application will not be accorded the priority dates. Such certified translation will be provided under separate cover.

Information Disclosure Statement

The Examiner indicates that references were received, but no forms PTOL-1449 accompanied these references. an Information Disclosure Statement with Forms PTOL-1449 was hand-delivered to the USPTO and stamped received by the Tech Center 1600/2900 on April 30, 2001. If this Information Disclosure Statement is not in the file, the Examiner is invited to call the undersigned.

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In view of the remarks herein, reconsideration of the requirement for election is requested and a resumption of prosecution on the merits are respectfully requested.

Respectfully submitted,
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By: _____
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